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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,007	05/02/2007	Mitsuharu Miwa	46884-5479	7737
55694	7590	01/26/2010	EXAMINER	
DRINKER BIDDLE & REATH (DC)			BRUTUS, JOEL F	
1500 K STREET, N.W.				
SUITE 1100			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005-1209			3768	
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			01/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,007	MIWA ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 October 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/17/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi (Pub. No.: US 2002/0013531).

Regarding claims 1-6, Hayashi teaches a sentinel lymph node detection system that anticipates the claimed invention. Hayashi teaches a near infrared fluorescent colorant indocyanine green is locally injected in advance into the vicinity of a tumor [see 0059, 0101]; and the fluorescent light emitted from the area of tissue under examination upon irradiation thereof by stimulating light is observed by use of a goggle type observation unit and detection of the sentinel lymph node is performed [see 0059].

Hayashi teaches the system comprises a fluorescent lamp, a stimulating light projecting unit which provided with a light source for producing fluorescent image observation using near infrared stimulating light [see 0060]; the lamp emits white light as illuminating light composed of visible light [see 0061]; the stimulating light is provided with a semiconductor laser for producing stimulating light having a wavelength of 790 nm and a light source driver [see 0062].

The observation unit comprises an objective lens, a near infrared cutoff filter, a half mirror, an eyepiece [see 0063] (eyepieces are made to be mounted on a head

portion of an observer). Hayashi teaches a near infrared cutoff filter light having a wavelength of 700 nm or larger and another near infrared cutoff filter cuts off light having a wavelength of 820 nm or smaller [see 0064]; a photographing unit (image pick up means) [see 0080-84]; A/D and D/A conversion circuits [see 0085], RGB decoder [see 0095-96], signal output from near infrared use a CCD is subjected to blanking, amplifying, double sampling clamping etc.., are use as to adjust a color of and a contrast (emphasis added); a monitor for displaying images [see 0100].

Hayashi discloses displaying a superposed image formed of the normal image composed of reflected illuminating light superposed with the fluorescent image, the examiner can observe the fluorescent image and the normal image at the same time, and the position of the sentinel lymph node contained within the area of tissue under examination can be easily confirmed [see 0044]. Superimposing the two images mean that they are overlapped (emphasis added).

Regarding claim 5, Hayashi teaches a fluorescent image memory for saving the digitized color image signal, a D/A conversion circuit, A/D conversion circuit [see 0085, 0094-996].

Regarding claim 6, Hayashi also teaches observation means consisting of a variety of optical means, a normal image optical path, and optical system for focusing [see 0078]. The sentinel lymph node is implemented in laparoscope comprises an

insertion portion, an illumination unit, a photographing unit [see 0080-84]; the insertion portion comprises a light guide [see 0082].

Response to Arguments

3. Applicant's arguments filed 10/06/2009 have been fully considered but they are not persuasive. The double patenting rejection of the previous office action is moot due to the amendment.

Applicant argues that Hayashi doesn't teach observation image in which fluorescent image and normal image are overlapped.

Examiner disagrees because with regard to overlapped images, Applicant discloses that normal and fluorescent images are mixed in video signal [see 0050, specification].

However, Hayashi discusses displaying a superposed image formed of the normal image composed of reflected illuminating light superposed with the fluorescent image, the examiner can observe the fluorescent image and the normal image at the same time, and the position of the sentinel lymph node contained within the area of tissue under examination can be easily confirmed [see 0044] and further teaches a superimposer 251 [see 0086]. Superimposing the two images means that they are overlapped (emphasis added).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768